DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
1350 Piccard Drive
Rockville, MD 20850

10/28/98

Dear Participants:

Welcome to OSB'S Outside Leveraging Seminar. We are pleased that representatives of other agencies, the Commissioner's Office, the Office of Regulatory Affairs, other centers, and other center for devices and radiological health Offices have joined OSB for this meeting.

Outside Leveraging (OL) is a term we have adopted to describe the creation of relationships and/or formal agreements with others outside CDRH to obtain services and/or support for little or no monetary exchange. The term OL embraces a continuum of projects from those where there is minimal outside assistance to the other end of the spectrum where most of the work and resources come from others outside CDRH, and/or FDA. These OL services will support our mission of postmarket surveillance and statistical support for regulation of medical devices to insure they are safe and effective.

We hope you find this seminar to be a source of inspiration. A videotape of today's proceedings will be available through CDRH's Staff College.

Outside Leveraging was one of the most challenging parts of our Strategic Plan for OSB managers and staff to consider. We have spent time in the past nine months learning about OL and now we are ready to share some of what we have learned with you.

We are very appreciative to those speakers from both inside and outside the FDA who have graciously agreed to share their OL experiences with us so that we may better understand the opportunities and challenges that OL presents.

Our primary goal at today's meeting is to inspire our own staff to create viable OL projects. We also wanted to include other invited guests with whom we might partner on OL projects, or who might use this seminar as a catalyst for initiating OL projects in their own offices.

We welcome your full participation and helpful insights during today's seminar and in the future as we pursue meaningful OL projects in OSB and perhaps in CDRH as well. Thank you for being here.

Larry Kessler, Sc.D.
Director, OSB

Patricia Spitzig,
Policy Analyst, OSB

TABLE OF CONTENTS

Special Thanks To:

The Outside Leveraging Committee

Mary Beth Abt
Midge Brier
Carol Herman
Mary Jones
Dan McGunagle
Suzanne Rich
Pat Spitzig
Marian Zellner

Speakers

Bob Pitulej, OSHA, Re-Invention Office
Chris Tirpak, U.S. EPA
Charles Winwood, U.S. Customs Office

Panelists

Greg Campbell, FDA, CDRH, OSB
Sharon Dillard, FDA, CDRH, OSB
Ruth Fischer, FDA, CDRH, OHIP
Adrianne Galdi, FDA, CDRH, OC
Cynthia Leggett, FDA, ORO
Robert McCleary, FDA, CDRH, OHIP
Russ Rutledge, FDA, CDER
Casper Uldicks, FDA, CDRH, OC
David Whipple, FDA, CDRH, ODE

Current Project Teams

Sue Ellen Bounds
Harry Bushar
Beverly Gallauresi
Ron Kay
Brenda Lucas
Dan McGunagle
Chris Parmentier
Howard Press
Pat Spitzig
Sonia Swayze

OSB's Strategic Planning and Goal Group 3

Kay Barrick
Mary Brady
Bruce Burlington
Susan Gardner
Larry Kessler
Wayne Robinson
David Shindell
Pat Spitzig

Other Key Contributors

Betsy Adams, FDA, ORA
Pat Bianchi, FDA, CDRH, OSM
Audrey Borgia, FDA, ORA
Diana Carpenter, FDA, CDRH
Debbie Cerra, FDA, CVM
Robert Diegelman, DOJ
Bea Droke, FDA, OC
David Feigal, FDA, CDRH
Linda Gangloff, FDA, OC
Jim Heslin, FDA, OC
Marge McAuliffe, FDA, OC
Elizabeth Jacobson, FDA, CDRH
Linda Kahan, FDA, CDRH
Russ Linden, R. Linden & Assoc.
Danitza Marinac-Dabic, FDA, CDRH
Jim McCue, FDA, CDRH
Terry McDonald, FDA, CDRH
Karen McFadden, DOJ
Lily Ng, FDA, CDRH, OSB
John O'Rangers, FDA, CV M
Gene Rouleau, Rouleau Assoc.
Karen Tapy, US Customs Service
Larry Tidmore, FDA, OC
Marie Urban, FDA, ORA
Pat Wood, Nat'l Performance Review
The Vice President's Office

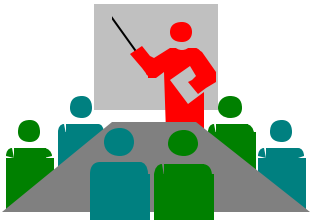
CDRH Supporters

Deb Blum
Chris Cole
Aaron Edmondson
Phil Frappaolo
Nicole Gill
Carolyn Hommel
Laura Josloff-Stewart
Ron Pytel
David Racine
Chet Reynolds
Karen Robertson
Joe Salyer
Mary Thomas
Nancy Wynne
Stephanie Yellin

And all those others who made these activities possible.

Seminar/Workshop Participants
Seminar Participants

Outside Leveraging



is a continuum

Outside Leveraging—the creation of relationships and/or formal agreements with others outside the Center for Devices and Radiological Health (CDRH) to obtain services/support for little or no monetary exchange. These services will support our mission of postmarket surveillance and statistical support for regulation of medical devices to insure they are safe and effective.

Selection Criteria For OL

We have developed some initial criteria for choosing potential OL projects:

a. There's a real payoff in saved money or time (cost-benefit).

b. The organization with which we'll be attempting "hand-off" already has at least a neutral, if not positive, relationship with OSB/CDRH.

c. The "process owners" inside OSB are supportive, or at least not hostile, to the concept of OL.

d. The issue being considered is not one which is currently "politically charged."

e. No conflict of interest, no appearance of conflict of interest.

Benefits from Leveraging

These are the reasons outside groups might work with OSB/CDRH as part of “Outside Leveraging” (OL):

User communities, industry, academics and others might participate in OL because:

- it gives them insight and understanding into FDA’s process; into the regulatory process.
- It allows them to “see inside” FDA’s door.
- It improves the chance for constructive dialogue.
- They might become part of the policy-making process in a more substantive way.
- They will directly benefit from the collaboration.

Industry might participate in OL because:

- (if there were more industry input into the MDR system, for example) there might be less concern that competitors were down playing their experience.

User communities might participate in OL because:

- they could amplify their voices and communicate their needs better to manufacturers/services of devices
- improve P.H.

Researchers and Academics might participate in OL because:

- there might be opportunities to engage challenging public health issues for faculty and students alike.

Resource Table

- Cooperative research and development agreements, "CRADA's" (background information on this funding mechanism)

- Books
  A. Imposing Duties by Malcolm K. Sparrow (purchased at Borders Book Store for $52.52). A book that approaches regulatory work in a new way.

  B. The Fifth Discipline by Peter M. Senge (purchased at Crown Books for $27.62). A book about systems thinking and learning organizations.

- Medical Device and Diagnostic Industry—10/98 trade press cover story re: HACCP and medical devices

- Re-engineering books (CDRH re-engineering staff and managers have The Blair House Papers, Reengineering the Corporation and Process Reengineering in Action.

- DOJ materials (videos, abstracts, case studies)

- OSB strategic plan

- OSB annual report

- CDRH policy on postmarket safety notifications

- CVM/New products: analysis by 3rd parties

- Standards Background Documents (from the web)

- ORA/State contracts and partnerships (from the web)

- EPA/Partnership program

Title of Project:

U.S. Customs Service Trade Compliance Partnerships and the Risk Management Process

Presenting Problem:

U.S. Customs Service's trade workload is expanding rapidly and there are no additional resources available. Customs also knows that approximately 18 percent of all imported cargo is in violation of at least one trade law. The only way to address this challenge is through innovative new programs and partnerships with private industry, other governments and other agencies.

OL Story

In the past 3 years, Customs has forged strong partnerships by:

? creating "accounts" with the largest importers,
? conducting industry round tables with key importing industries and implementing joint action plans, and
? sharing data and conducting joint enforcement efforts with other agencies and other governments.

Lessons Learned

? The agency must convey a clear message.
? It is impossible to communicate too often or too directly.
? Commitment and day-to-day involvement of top management is crucial.
? The agency must constantly evaluate partnership programs and be willing to regroup when necessary.

Results/Benefits to Private Industry

? Provides a primary point-of-contact within the agency
? Helps resolve cross-port uniformity problems
? Issues are formally identified and scheduled for resolution
? Quick access to information about new Customs programs
? Possible reduction in cargo release cycle times

Results/Benefits to U.S. Customs Service

? Increased uniformity
? Customs personnel gain knowledge of account and industry issues
? Permits focus on importers with the highest risk
? Facilitates informed compliance and reasonable care

Biography

Charles W. Winwood
Assistant Commissioner
Office of Strategic Trade

Mr. Winwood, Customs leading process management champion, is the Assistant Commissioner, Office of Strategic Trade, for the U.S. Customs Service. In this role, he directs all strategic analysis and planning for Customs trade compliance efforts. He is also the Process Owner for Customs trade compliance process. He is currently leading the complete redesign of this process—Customs' largest. In this role, he chairs a cross-functional Board of Directors and is responsible for all national policy direction and implementation.

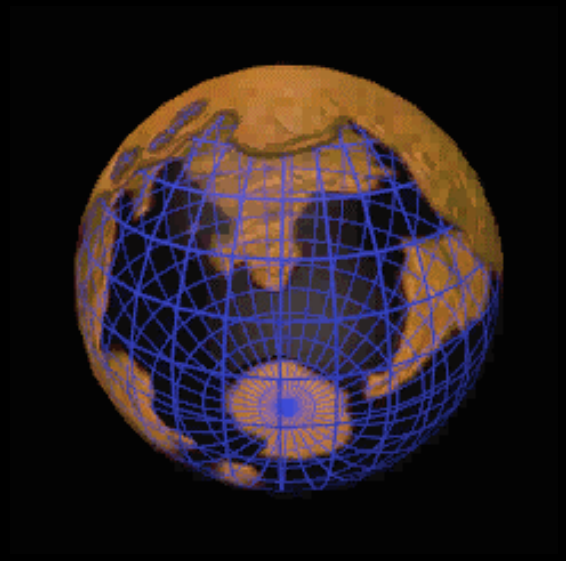
Prior to his appointment to the Office of Strategic Trade, Mr. Winwood led the Office of Processes and Policy. His responsibilities included the process management and policy development of Customs three core processes: trade compliance (cargo importation), passenger, and outbound.

In his 26 years with the Customs Service, Mr. Winwood has served in the management positions of Assistant Commissioner, Office of Inspection and Control; Assistant Regional Commissioner, Operations, Southeastern United States; Regional Director, Office of Inspection and Control; and Assistant Airport Director, Miami International Airport.

Mr. Winwood began his Customs career in 1972 as a Customs inspector after serving 2 years in the United States Army.

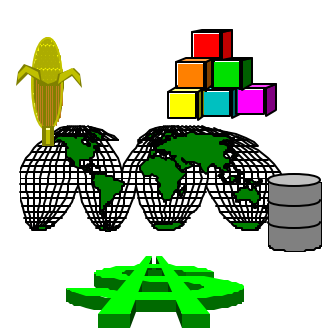
A native of Pennsylvania, Mr. Winwood received a Bachelor of Science Degree in Political Science from Indiana University of Pennsylvania in 1969 and obtained a Masters Degree in Management and Public Administration from Florida International University in 1976. In 1984 he was selected for the Senior Executive Fellows Program in the JFK School of Government at Harvard University. In 1994, Mr. Winwood received the Federal Executive of the Year award from the Federal Executive Institute.

United States Customs Service

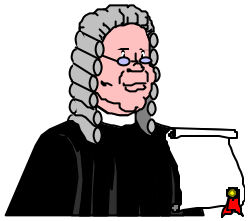


Trade Compliance Partnerships and the Risk Management Process

Elements of Change

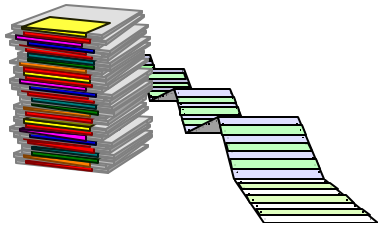


World Trade



Legislation

Performance Expectations



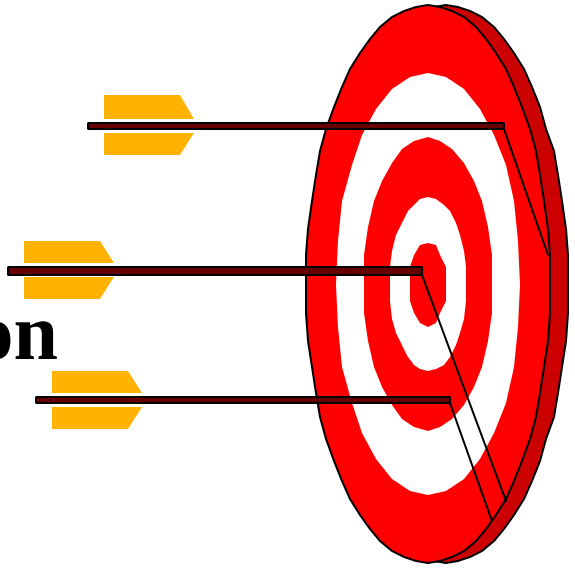
Data/ Information

Increased Workload

Tight Budgets

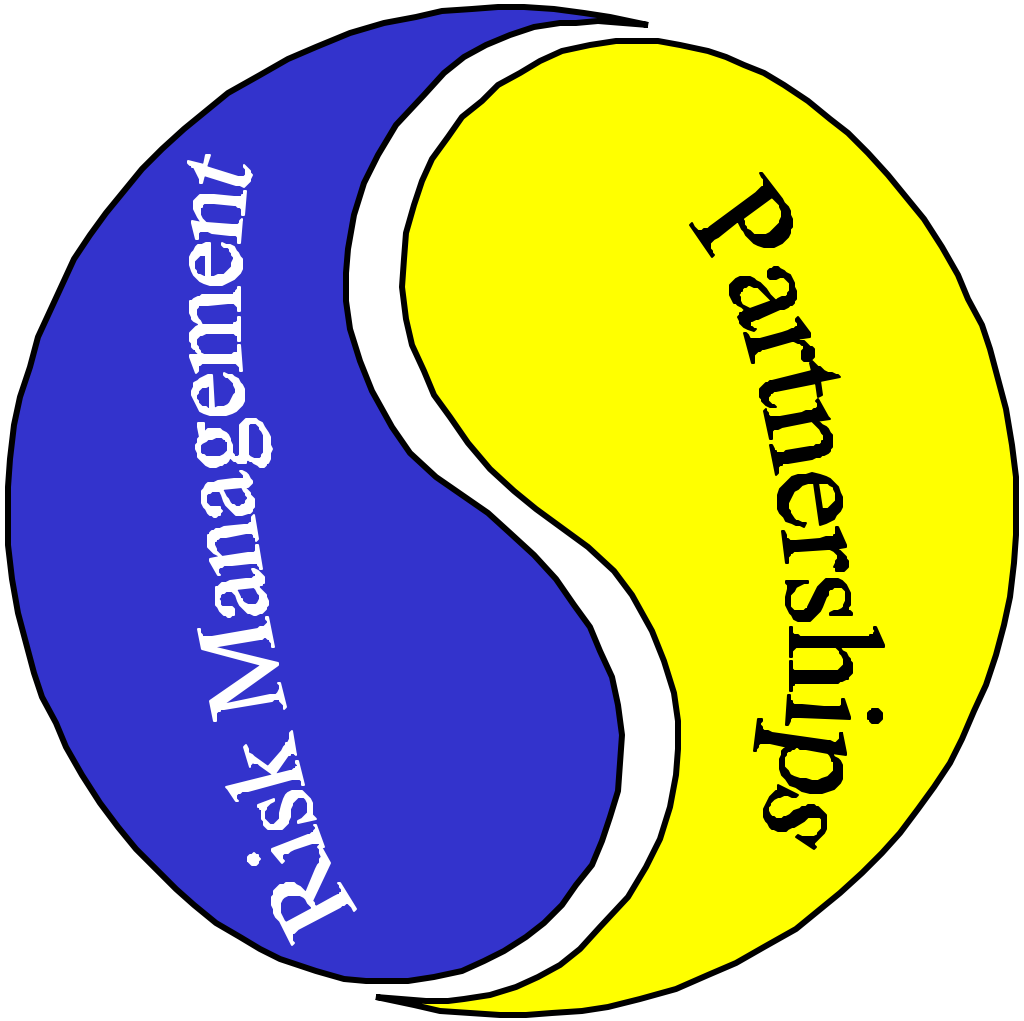
U.S. Trade Compliance Goals

- Achieve 90% overall trade compliance
- Achieve 95% compliance in primary focus industries
- Maintain collection of at least 99% of the revenue
- Reduce cargo release cycle time for compliant imports
- Increase customer satisfaction
- Reduce cost per transaction

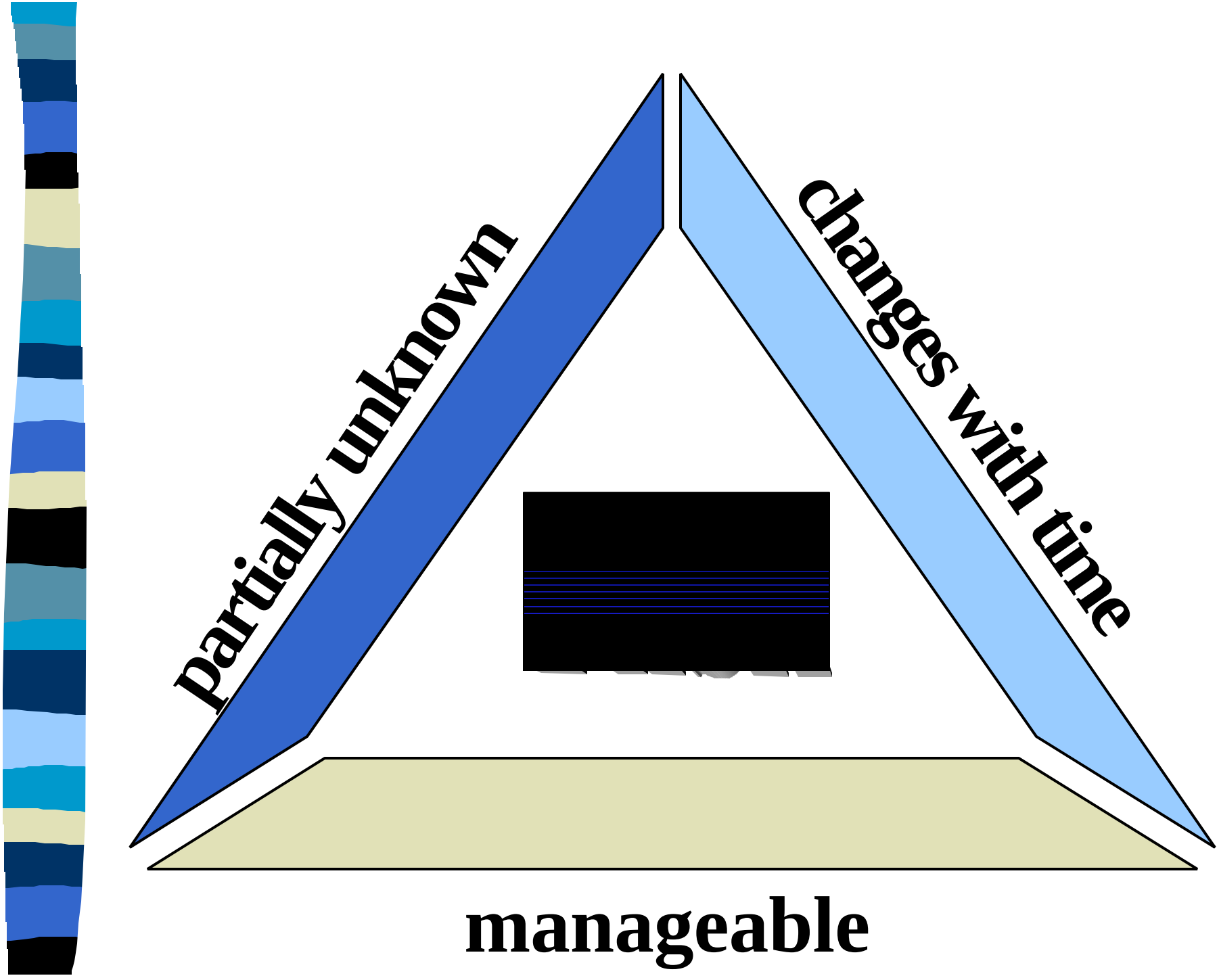


The Challenge

- More than 34 million lines of cargo
- Approximately 5.5 million projected discrepancies
- Resources to conduct 600,000 exams

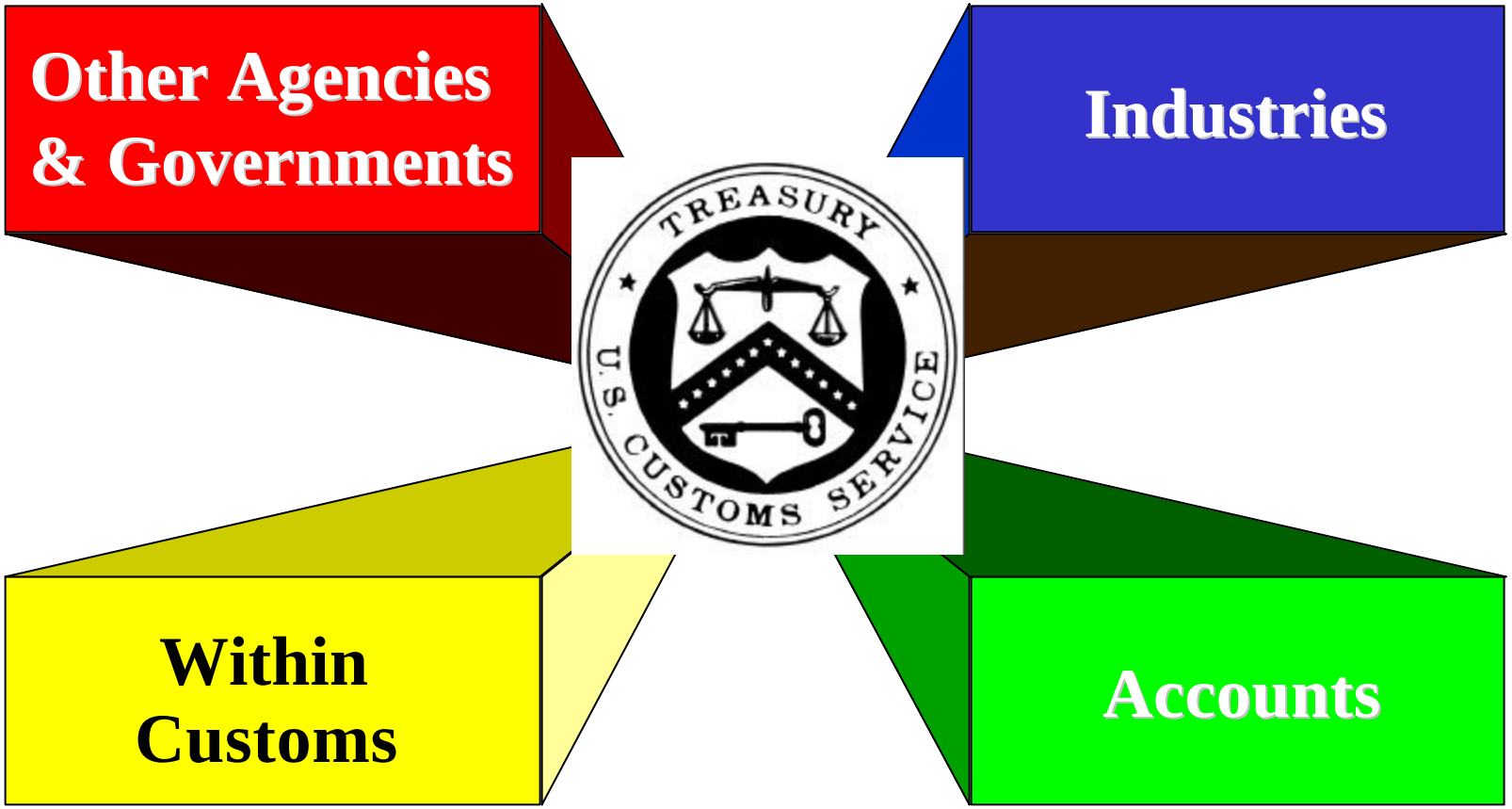


Trade Compliance Success


partially unknown
changes with time
manageable

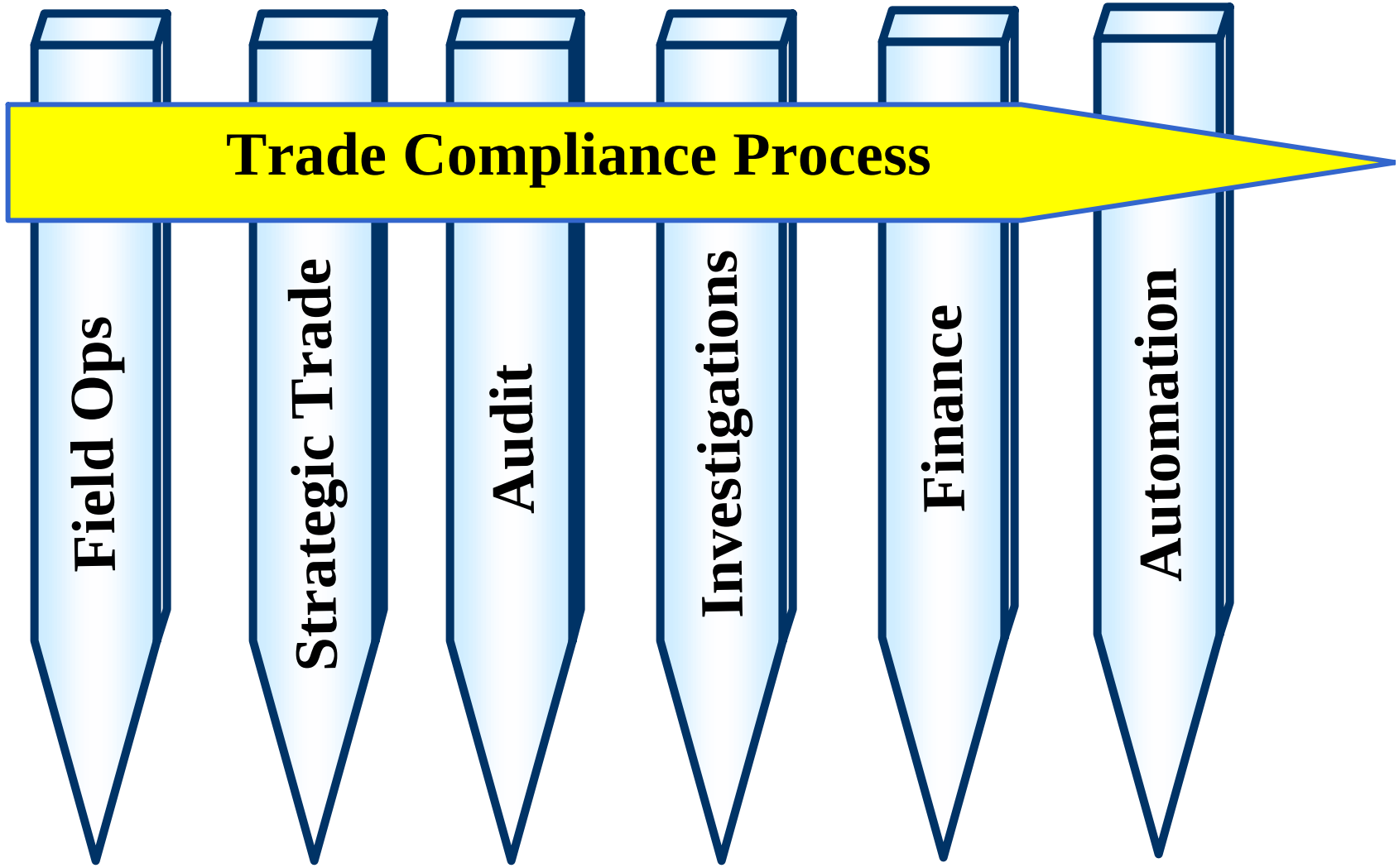
Risk Management Process

Partnerships



Partnerships

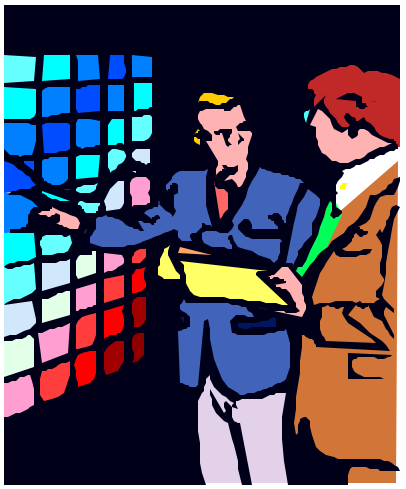
Within U.S. Customs

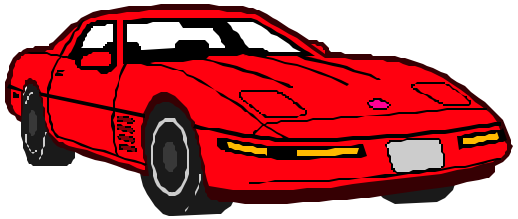


Partnerships

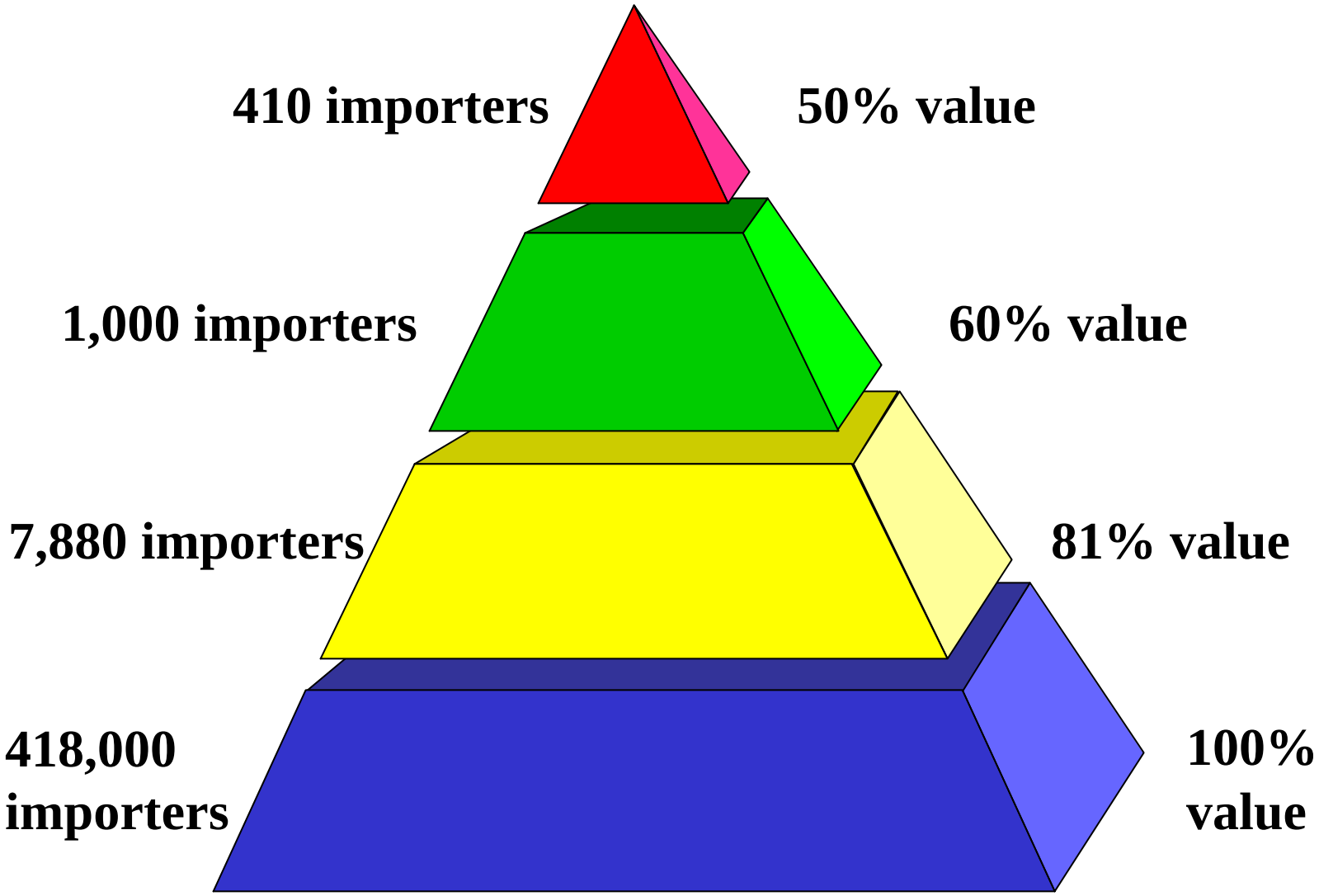
Industry

- Industry Roundtables
- Joint Action Plans
- Education
- Conferences



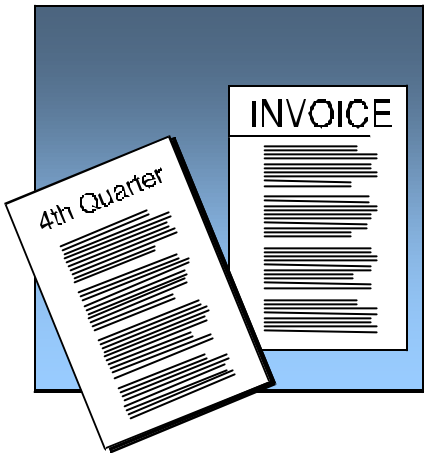


Account Management



Partnerships

Accounts

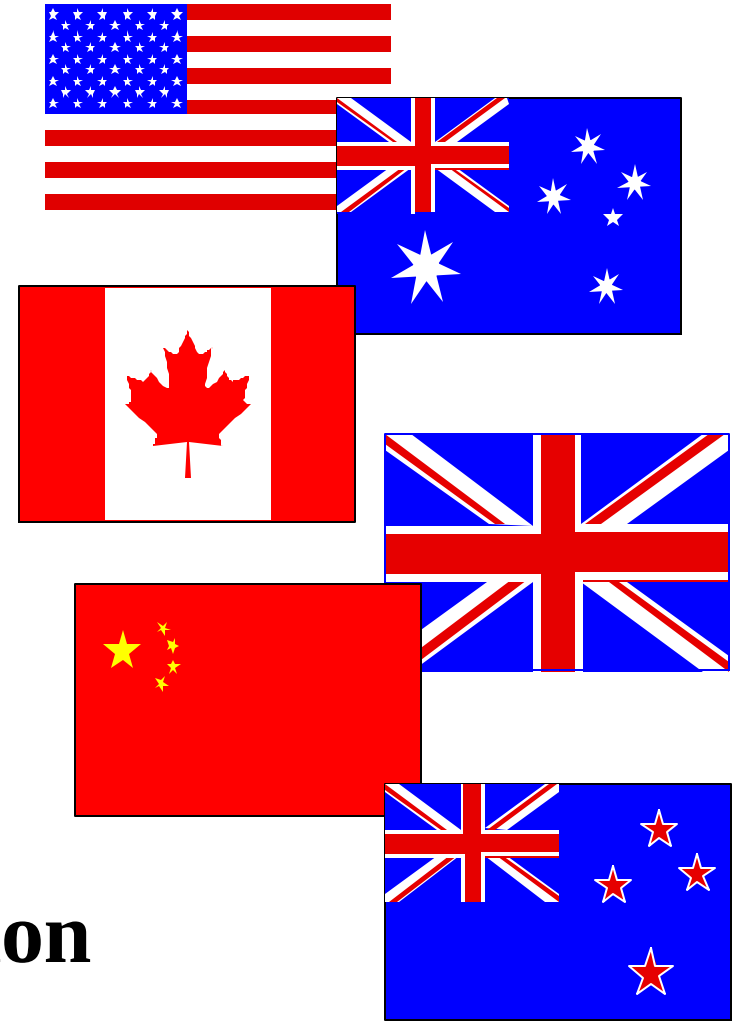


- Account Management
- Compliance Assessments
- Importer Compliance Monitoring Program
- Sharing Data
- Building New Systems

Partnerships

Other Agencies and Other Governments

- Measurement
- Resource-sharing
- Enforcement Efforts
- Data Sharing
- Best Practices/Education



Lessons Learned

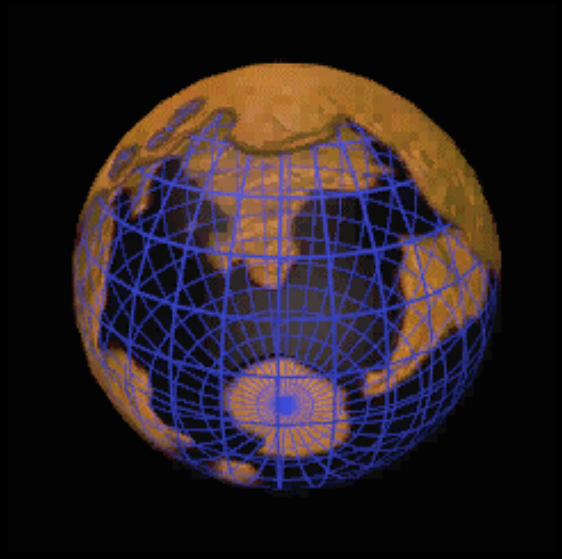
Must convey a clear message

Impossible to communicate too often or too directly

Commitment and day-to-day involvement of top management is crucial

Must constantly evaluate and be willing to regroup when necessary

United States Customs Service



Charles W. Winwood

Assistant Commissioner

Office of Strategic Trade

202-927-0570

Appendix 11: Manual for the 10/28/98 O. L. Seminar Tab 2

Title of Project: From Confrontation to Collaboration—Partnering

Presenting Problem:

Outside Leveraging Story: US-EPA's 33/50 Program
U.S. Vice President's Common Sense Initiative

Lessons Learned:

- Partnerships can accomplish what cannot be done alone
- Problem solving dynamics differ from liability avoidance
- Stakeholder participation widens the range of options
- Stakeholder participation promotes "buy-in"
- Affected parties are stakeholders with "customer" views
- Empowerment of affected parties solves problems on-site
- Aging baby boomers are changing profile of stakeholders
- Positive reinforcement first—back up with negative sanctions
- Regulatory body can have two arms: incentives and sanctions
- New initiatives need Champions
- Balancing disclosure with the right to know and trade secrets
- Information technology is redefining relationships

Obstacles:

- Government bureaucracy is old and values stability
- Tradition of command and control regulations
- Legislation—Regulation—Litigation cycles go in circles
- Lawsuits pull funding away from cleanups
- Rethinking incentives (i.e. absence of stick is not carrot)
- Special interests upwind, uphill and upstream
- Disadvantages downwind, downhill, and downstream
- Language barriers: tech-jargon and legalese
- Powershifts as agency roles change from regulator to resource
- Fear of failure or rejection or the unknown
- Consensus vs. unanimity—dealing with veto power

Results/benefits to OL partner:

- collaboration is more productive than confrontation
- united we stand, divided we fall
- participative democracy promotes buy-in
- development of productive working relationships
- understanding expectations of former adversaries
- economies of scale

Results/benefits to regulatory agency:

- more can be accomplished with fewer resources
- priorities can be set with a sense of proportion
- problems solved on-site don't become national
- building civic capacity to solve problems on site.

From Confrontation to Collaboration—Partnering

Partnerships provide opportunities for reinventing traditional models of government to meet the public service needs of our country's growing population.

Partnering is about coming together to accomplish what cannot be done alone. The synergy of partnerships; leads to all kinds of benefits, such as economy of scale. Partners have many identities: individuals or organizations, such as government agencies, businesses, trade organizations, public interest groups, and others. The key to partnering is common ground.

Regulatory partnerships pose particularly interesting challenges. Partnering with the regulated community requires a significant change in mindset and dynamics, especially on the part of traditional government regulators. Enforcement officials in particular have difficulty separating violations from violators. Traditional adversaries on opposite sides of an issue generally have a hard time appreciating each other's point of view. Yet, it is precisely such appreciation that can open the gate to previously unrecognized possibilities. A change in mindset often leads to a change in dynamic from confrontation to collaboration; from hostility to cordiality; from liability avoidance to regulatory problem solving; from "gotcha-so-sue-me" to "let's-work-this-out". Not so easy, but well worth the effort because the proliferation of regulatory lawsuits are diverting more time and tax dollars into courtrooms and away from compliance. Court agendas are severely overcrowded. Time to explore life outside the courtroom. Time for a change.

If regulators could become resources for empowering the regulated community to deal directly with their own public interest problems, such as threats to the health and safety, on site, where they happen, the problems wouldn't grow to national proportions. Why couldn't the legalese, science and techno-jargon of regulations be replaced with plain English instructions that anyone could use?

Corporate America has certainly matured with the baby boomers and stands ready to take wider responsibility for its products, processes and personnel in rather unprecedented ways, including even partnering with its government regulators. Traditional regulation is running into the law of diminishing returns on the negative sanctions front. Positive reinforcement is under-explored in regulatory agencies, due in part, to a seldom articulated general unease among regulators with the concept that too many incentives somehow devalue their impact. According to Vice President Gore, it's time to update that thinking and explore the value-added of positive reinforcement as "engines for change". The American Boy Scouts have been using badges as ways to acknowledge skill development, so is there really any valid reason why regulatory agencies couldn't develop awards in a similar fashion to acknowledge the development of corporate skills in the regulatory arena as they emerge?

Charter for Coordination of EPA's Partnership Programs

PURPOSE

This charter establishes an operating structure for internal coordination and communication related to EPA's partnership programs. Coordination among EPA's partnership programs is conducted by the Partnership Programs Coordinating Committee (PPCC) and the Reinvention Action Council (RAC) Advisors (a subcommittee of RAC), and is managed by the Office of Reinvention (OR).

EPA's partnership programs work with external partners to demonstrate that voluntary goals and commitments achieve real environmental results in a timely and cost-effective way. Through its array of partnership programs, collectively referred to as Partners for the Environment, EPA works cooperatively with industry and others to effect long-term institutional changes. The partnerships result in improved public health and environmental protection and are mutually beneficial by preventing pollution at lower costs.

SCOPE

Role of the PPCC

The Partnership Programs Coordinating Committee (PPCC) will be responsible for coordination, communication, marketing, measurement, identification and evaluation of cross-cutting issues, and development of policy and implementation guidance. The PPCC fosters coordination and internal communication among partnership programs, avoids duplication of efforts and services, improves resource utilization, and promotes common approaches to evaluation and performance measurement. It also provides a means to consolidate the Agency's message and market the programs in a way that reduces confusion about the number, scope and purpose of partnership programs. Specifically, the PPCC will:

- ? Provide up-to-date information on partnership programs and their successes; jointly market Partners for the Environment programs;
- ? Identify and address cross-cutting policy issues as needed and recommend options to the RAC Advisors;
- ? Review and provide advice to new partnership programs to ensure coordination and consistent external communication; and
- ? Prepare guidance on development, implementation and evaluation of partnership programs.

Role of OR

The Office of Reinvention (OR) will oversee policy on partnership programs and facilitate both policy and coordination issues. Specifically, OR will:

- ? provide day-to-day management of PPCC functions and maintain a central repository of information on partnership programs;
- ? coordinate with the PPCC to support new partnership programs;
- ? serve as the initial Agency contact for general inquiries about partnership programs;
- ? identify cross-cutting policy issues, assist the PPCC and RAC Advisors in resolution of issues as needed, and involve or inform the RAC and AAs; and
- ? ensure that evaluations are conducted by the partnership programs and reviewed for improvements in how the Agency does business.

Role of RAC Advisors

The RAC Advisors, a subcommittee of the Reinvention Action Council (RAC), will assist OR and the PPCC by providing senior management advice and guidance on partnership programs policy and coordination issues. The RAC Advisors will:

- ? be advocates for the partnership approach;
- ? identify and frame the major cross-cutting issues, deciding whether the PPCC, OR, the RAC Advisors or another office will be responsible for analysis and recommendations;
- ? make decisions or elevate partnership program policy or management issues;
- ? ensure timely and effective implementation of policy decisions by the partnership programs and the RAC; and
- ? ensure that the RAC makes resources available to conduct activities to promote and improve partnership programs.

Composition

All partnership programs are required to be represented on the PPCC. Offices/Regions with multiple partnership programs shall designate a lead representative responsible for insuring coordination and providing information. Programs may also be represented on the PPCC by national partnership program directors. The Deputy Associate Administrator for Reinvention Policy is the permanent co-chair of the Partnership Programs Coordinating Committee. Another senior EPA official, such as a Deputy Regional Administrator or a Deputy Assistant Administrator, serves as co-chair on a rotational basis for a two-year term. Co-chairs will provide staff support for the activities related to partnership coordination.

The RAC Advisors shall have no more than six members and shall include representation from Regions and Headquarters Offices that support several partnership programs. The

Deputy Associate Administrator for Reinvention Policy will be a permanent member of the RAC Advisors; all other members will serve for a term of two years and may be re-appointed by the Associate Administrator for Reinvention.

MEETINGS

The PPCC shall meet monthly to conduct its business. Work groups and subcommittees of the PPCC shall meet as needed. The Co-chairs or their designee shall attend the PPCC monthly meetings and shall meet with PPCC members and subcommittees as needed. The RAC Advisors shall convene as necessary upon the request of the Co-chairs, the PPCC and/or OR.

DURATION

Coordination of EPA's partnership programs will be needed on a continuing basis as determined by the Administrator or Deputy Administrator. This charter shall be reviewed five years after approval.

_____ _____

Fred Hansen, Deputy Director Date

EPA website:

www.epa.gov/ooaugeag/partners/metrics.htm

Appendix 11: Manual for the 10/28/98 O. L. Seminar Tab 3

Abstract – OSHA, Reinvention Office

Title of Project – OSHA Shifts from Reactive Solutions

Presenting Project – Bob Pitulej, OSHA Reinvention Office

Outside Leveraging Story: OSHA seeks to have its regulated community choose the type of OSHA they would like to deal with – for employers willing to develop and further improve their worker safety and health programs, offer partnerships, outreach, and consultation; for employers with a negative record of concern for worker safety and health, continue to respond with comprehensive inspections, citations, and criminal prosecution.

Lessons Thus Far:

- focus on performance more than process
- maintain an enforcement presence
- flexibility in implementing the GRIP Model
- ensure managers are involved and accountable
- work in partnership with your internal unions
- communications, communications!
- Unified message from all levels of OSHA
- Set realistic and measurable goals
- Realize change is difficult
- Maine 200 – local unions vs. national unions

Obstacles that Must be Overcome:

- overcoming the current court stay (December 1998)
- establishing consistency in delivering the program

Results/Benefits to OL Partner

- increased worker safety and health
- partner decides the type of OSHA they want to interact with
- $ savings in insurance, worker's comp., etc.

Results/Benefits to OSHA

- increased worker safety and health
- targeted use of limited OSHA resources (human, financial, time)

The New OSHA:
Common Sense @ Work

G etting

R esults and

I mproving

P erformance

OSHA's Mission

Assure so far as possible every working man and woman in the Nation safe and healthful working conditions

The diversity of occupational safety and health challenges facing OSHA in the 21st century does not permit us the luxury of having only hammers in our toolbox of capabilities.

Why OSHA Needed to Change:

? OSHA needed to expand its use of tools to supplement strong enforcement
? Current targeting system did not get OSHA to the worst actors
? Performance Measures stressed activities, not results
? The GAP between responsibilities and resources
? The full value of safety and health in the workplace is not recognized

Why OSHA is Changing

? GAP between mission and resources:
6 million injuries, 6 thousand deaths; over 95 million workers
approximately 1,231 inspectors
? Stakeholder & Congressional dissatisfaction
? New & complex hazards require different strategies
? Workplace injuries and illnesses cost the economy $171 BILLION OSHA's budget is approximately $336 million

OSHA's Vision

? To be a world class leader in occupational safety and health by making America's workplaces the safest in the world
? To eliminate workplace injuries, illnesses, and deaths
? Workplace environments characterized by a genuine, shared commitment to workplace safety and health by employers and workers

OSHA's Strategic Plan

- **GOAL 1: Improve workplace safety and health for all workers, as evidenced by fewer hazards, reduced exposures, and fewer injuries, illnesses, and fatalities**
- **GOAL 2: Change workplace culture to increase employer and worker awareness of, commitment to, and involvement in safety and health**
- **GOAL 3: Secure public confidence through excellence in the development and delivery of OSHA's programs and services**

Linking Strategic Plan and GRIP the *Challenge*

- **Area Office staff are responsible for implementing many of the strategies outlined in strategic and performance plans**
- **Apply reinvention tools and techniques to accomplish strategic goals and objectives**
- **Share "best practices" from local initiatives across Regions**

GOALS for a Revamped OSHA Field Office

- **Reduce workplace injuries, illnesses and deaths**
- **Improve the quality and timeliness for delivery of service**
- **Develop a capacity to proactively solve problems, not just respond to them**
- **Focus on the worst actors and hazards**
- **Increase the types of compliance assistance provided to employers**

The New OSHA Field Office What's Different?

- **New Strategy**
- **New Organizational Structure**
- **Enhanced Measurement Systems**
- **Process Improvements**

OSB Outside Leveraging Seminar

"Development of National and International Standards An OL Perspective"

by
David M. Whipple
Associate Director
Division of Ophthalmic Devices
Office of Device Evaluation

Presenting Problem:

The Division of Ophthalmic Device (DOD), like other divisions in ODE was faced with an increasing number of regulatory submissions and marketing applications (e.g., IDEs, PMAs and 510(k)s) in a time of consistently diminishing resources. Chronic backlogs of overdue applications existed in many divisions throughout the 1980's and early 1990's as we struggled to meet the statutory deadlines for processing applications. It was clear that we needed to identify new ways of getting our work done and seeing that new and improved technologies reached the market place as quickly as possible. We needed to become more efficient in the review process; to focus our limited review resources on mature technologies with risks that could be managed through "special controls"; to simplify regulatory submissions and possibly eliminate the need for certain types of incoming applications for less risky devices; but, without compromising our mission to public health and safety.

Many new initiatives were embarked upon in the early 1990's as a part of our mandate from Congress though the Safe Medical Devices Amendments Act of 1990. DOD was one of the first divisions in ODE to actively explore the use of national and international standards in our review process as a means of improving our efficiency and our approach to regulating ophthalmic medical devices.

Outside Leveraging Story:

In 1991, I was involved in exploring the use of consensus standards to develop "special controls" for reclassification of contact lens products. At that time, contact lens devices were regulated as Class III PMA products. Hundreds of PMA applications were being processed each year for these devices. In previous years, these devices were the subject of a huge backlog and 3 year review delays were not uncommon. These devices were

perfect candidates for reclassification from Class III into Class II through the use of "special controls." If reclassification were successful, the resources needed to process 510(k) for contact lens products would be much less and could be shifted to work on the higher risk PMA devices such as excimer lasers for refractive surgery.

I began working with the American National Standards Institute (ANSI) and the International Organization of Standards (ISO) in 1991 in an effort to understand the standards process and determine if this approach could be used in our reclassification effort. At the same time, another member of our division, Mr. Don Calogero, also began working with standards for intraocular lenses for many of the same reasons. IOLs are also regulated as Class III PMA devices for which we receive hundreds of IDEs and PMAs each year. The results of my findings and lessons learned from this experience will reflect our efforts in both areas.

Lessons Learned:

- Use of consensus standards can be a very valuable tool for regulating medical devices, especially when incorporated into a guidance document for a specific device type. They can be successfully used in the development of "special controls" for use in reclassification of devices.
- Declaring conformance to recognized standards can significantly improve the efficiency of the review process and results in significant time savings for reviewers. This is especially true for methodology standards, i.e., sterility, disinfection, etc., that eliminate the need for large amounts of validation data and require huge amounts of review time.
- Developing standards can be a long and difficult process; don't expect immediate results or a quick return on your investment going down the standards development path. For short term needs, work with existing standards rather than developing new ones from scratch.
- Working on standards can be time consuming and costly; pick the work carefully using the principle of "getting the most bang for the buck." There is limited utility for some standards in the regulatory process.
- Harmonization is most successful when bargaining from a position of strength. FDA regulations and guidance documents are often used as a basis for developing national or international standards.
- Harmonization of standards doesn't always mean full agreement with our regulations or guidance documents. FDA is one voice—one vote in the standards process. Be flexible and open-minded enough to recognize good science and accept our need to change.
- The development and use of consensus standards is mandated by Congress in the FDA Modernization Act (FDAMA) of 1997 and is the wave of the future for countries throughout the world. Take the opportunity to understand the process and begin working with standards now.
- Rules of the game are still evolving around the world (e.g., formal declaration of conformance to a FDA recognized standard vs. certifying compliance with an applicable voluntary standard).

Obstacles That Must Be Overcome:

- National laws and regulations can be impediments to international harmonization of requirements.
- Limited CDRH resources can limit your involvement. Standards budget is limited and competing priorities at the Center level may not justify the funding. Funding may have to come from the office or the divisional budget.
- Participating in standards development requires an investment of time and resources. Selecting the right person to do the job is critical. Successful standards development involves political and negotiating skills as well as technical expertise.
- Timeline and priorities for standards development are not under FDA's control. FDA is one voice—one vote in the standards process.
- Companies are often reluctant to release or share data for standards development.
- Language barriers on an international level can be problematic. Definitions and terminology differences within standards are often complicated and difficult to resolve.
- Overlapping standards can be confusing and create more problems than they solve (e.g., Vertical Standards vs. Horizontal Standards).

Results/Benefits to OL Partner:

- Enormous savings in time and money for companies. Standards can be used to eliminate the need for redundant testing, reduce trade barriers and level the playing field of competition for manufacturers.
- Adopting consensus standards at the national and international levels provides a basis for consistency in safety and performance expectations for similar devices around the world.
- Better predictability in the timeline for gaining FDA marketing approval. Use of standards has contributed to simplified submissions and much quicker review times for applications.
- Use of standards has fostered the development of more product-specific guidance documents. The documents have been used for reclassifying devices or exempting devices from premarketing submissions.

Results/Benefits to FDA:

- Use of national and international standards in our regulatory process has contributed to the elimination of all backlogs in DOD, improved review times for all types of applications, and has contributed to the elimination of certain types of incoming applications (i.e., Class I and Class II exemptions).
- Reclassification of daily wear contact lenses (1994) and contact lens care products (1996) using guidance documents containing references to acceptable testing standards has streamlined the review of 510(k)s for these products. It has allowed us

to shift review personnel into the higher risk, newer technology areas such as the excimer lasers for vision correction.

- We are meeting the mandate of Congress for use of standards in the US regulatory process. Published a list of 12 recognized standards in 1997 for use in contact lens product applications including clinical trial designs and fundamental requirements for contact lens products.
- Use of standards is an effective regulatory tool streamlining the review process and has contributed to our ability to develop product-specific guidance documents as special controls for reclassifying or exempting devices.
- Personal and professional benefits include the ability to influence and establish public health and safety standards on an international level; the opportunity to gain experience with the standards development process; the opportunity to demonstrate leadership and positive image for CDRH; and, the opportunity to understand others' needs and goals around the world, a professional learning experience that is unmatched anywhere else in FDA.

DAVE WHIPPLE

Biography

Mr. Whipple begins his 22nd year of continuous service with the FDA and his 18th year in the Division of Ophthalmic Devices (DOD). He holds degrees in both biology and laboratory technology and is registered with the American Society of Clinical Pathologists and a member of the Regulatory Affairs Professional Society. Mr. Whipple began his career with FDA in pharmacology and toxicology research with the Center for Veterinary Medicine before coming to DOD as a review scientist in 1980. He became Branch Chief for Contact Lens Products in 1987 and is currently the Associate Director in DOD, a position he has held for the last 7 years. Mr. Whipple has been involved in standards development for CDRH since 1991. He is a CDRH liaison representative to the American National Standards Institute (ANSI) and an accredited ANSI delegate to the International Organization for Standards (ISO) for the development of international standards for ophthalmic devices. Mr. Whipple has received numerous awards and honors in his FDA career including the CDRH Excellence in Review Science Award and FDA Award of Merit.

TITLE: COOPERATIVE AGREEMENTS WITH NON-PROFIT GROUPS AND OTHER AGENCIES TO PRODUCE PUBLIC HEALTH TELECONFERENCES

Robert McCleary

BACKGROUND:

Seven years ago, CDRH elected to move into the world of satellite-delivered teleconferencing. Even though the "teleconference" had been an established communications tool for more than twenty years, with private or closed networks proliferating the corporate world and some government agencies, it was new territory for FDA.

OUTSIDE LEVERAGING:

While CDRH was confident it could produce the programming, it was not equipped nor financially prepared to create the ad hoc network (downlinks) necessary for the reception of the programming. Partners were needed to complete the team. Natural divisions of labor begged for outside participation.

LESSONS LEARNED:

CDRH is now one of the premiere broadcast teleconferencing centers in the federal government. Both public health agencies as well as other federal groups seek its services. This singular position in the competitive world of government communications could not have been attained without the invaluable contributions made though partnerships. It has become a rare "win-win" situation for both CDRH and our association partners. These same working relationships have also been superimposed upon joint-government projects with similar success. Latex is the most recent example.

OBSTACLES:

The world "ain't" perfect. Don't get me started.

RESULTS/BENEFITS:

The benefits far outweigh the liabilities. Cost savings to FDA are substantial. But there is much work that can be done to make the partnerships even more rewarding. The needs of the partners are not universal. One size does not fit all. Satisfying everyone is an important, necessary, and difficult task. Let's talk.

Biography

Robert F. McCleary, Ph.D.

Robert F. McCleary, Ph.D. has been involved in television for more than thirty years. He has served as a television writer, producer, director, academic administrator, corporate office and currently is the director of the Division of Communication Media with the Food and Drug Administration. McCleary received his doctorate in Communications from Ohio University in 1978. For more than sixteen years Dr. McCleary was actively involved in the production and management of educational television programming for the University of Maryland. He also served as the academic director of the school's television curriculum. Before joining FDA, McCleary served as a media consultant, and was a founding officer of the Discovery Channel. Dr. McCleary has produced and directed programs for international companies, national training teleconferences for numerous government agencies, and directed for the British Broadcasting Corporation, The Discovery Channel and Courtroom Television Network.

TITLE OF PROJECT:

INTERNATIONAL EDUCATION TELECONFERENCE
NATURAL LATEX ALLERGY: RECOGNITION, TREATMENT, & PREVENTION
Live program aired on May 5, 1998

Project Manager:
Sharon F. Dillard, M.S., ARRT(N), CNMT
FDA/CDRH/OSB/DPS

PRESENTING PROBLEM:

Natural latex/rubber allergy is an emerging public health issue. In order to minimize or prevent natural latex allergy related morbidity and mortality, it became clear to FDA that health care professionals and others needed timely access to factual information on regulatory, scientific, and clinical aspects of this topic. Evidence indicated that there was no single reliable information source that could provide a comprehensive overview of these topic areas.

OUTSIDE LEVERAGING STORY:

In response to the information need expressed by health care professionals and others concerning natural rubber latex allergy, the United States Food and Drug Administration's Center for Devices and Radiological Health initiated an innovative collaboration between 17 major Federal and non-Federal stakeholder organizations. The goal was to develop and fund a live, interactive satellite down-linked educational teleconference on natural latex allergy.

Five Federal Agencies considered major stakeholders in the issue met and each agreed to commit $8,000.00 to cover the production costs of the program. However, the actual production costs associated with a live satellite teleconference are typically small when compared to the actual "down-link side" cost requirements associated with satellite based programming. In the recent past, Federal Agencies such as CDC, have spent between $100,000 and $500,000 to handle smaller educational outreach efforts that required the Federal Agency to assume the total costs and staff activities associated with an educational program of this caliber. Large "down-link side" costs are typically associated with the following tasks:

- Funding the expenses of participating topic area experts
- Obtaining adequate satellite time and geographical coverage
- Registering & arranging "down-link" or broadcast viewing sites in sufficient quantity for convenient target audience access
- Advertising and marketing the educational program

- Continuing professional education accreditation activities
- Receiving and scoring program evaluations
- Developing and mailing supporting educational material

Non-Federal organizations invited to participate in this project were told that program production costs would be funded by various Federal "stakeholder" organizations. The invited non-Federal participants were challenged to work to develop a plan, independent of the need for government funding, that would cover the "down-link side" costs and activities associated with the project. All invited organizations agreed to participate and in late October 1997, the first organizational meetings were held. As a result of the collaborative efforts of both participating and endorsing organizations, this award winning live teleconference aired 7 months later on May 5, 1998. This program reached possibly the largest live audience of multidisciplinary health care professionals in the history of public health education teleconferencing.

LESSONS LEARNED:

- It can be done!
- Organizational & topic area champions are essential
- The project model is viable
- Consult ethics contacts when working with non-federal organizations
- Verbal resource commitments from partner organizations with no direct financial commitment to the project can be problematic
- Logistics and administrative tasks are formidable
- Improved communication and goodwill are intangible benefits associated with collaborative efforts of this magnitude
- Success can create new opportunities to creatively address other organizational needs

OBSTACLES THAT MUST BE OVERCOME:

- Successful "down-link side" cost recovery strategy must be developed
- Need to eliminate or substantially reduce the inter-agency surcharge associated with IAG fund transfers
- Development of a viable partnership/consortium format
- Need to identify & cultivate organizational champions
- Program marketing activity timelines must be optimized

RESULTS/BENEFITS TO OL PARTNERS & TO FDA:

Generic results and benefits to participants included:

- Increased ability to quickly and cost effectively reach large multidisciplinary international audiences on emerging public health topics
- Resource optimization/improved customer service
- Improved communication between stakeholder organizations
- Creation of new opportunities

Upcoming meetings between Federal and non-Federal stakeholder organizations will be held in order to review the project reports and program evaluations associated with the latex allergy teleconference pilot and to determine whether or not this public/private sector partnership arrangement can be formalized into a viable consortium. The primary goal of this continued effort is to increase each organization's ability to provide their customers with convenient, high quality, and cost effective public health education on important topics of multidisciplinary interest.

BIOLOGICAL SKETCH

Sharon F. Dillard, MS., ARRT(N), CNMT
Senior Scientist
Division of Postmarket Surveillance (DPS), Office of Surveillance and Biometrics (OSB)
Center for Devices and Radiological Health (CDRH),
United States Food and Drug Administration (FDA)

1350 Piccard Drive (HFZ-520)
Rockville, MD 20850
Phone: 301-594-3585
Fax: 301-594-1967
E-Mail: **sfd@cdrh.fda.gov**

Sharon Dillard is a senior scientist within the Division of Postmarket Surveillance (DPS) in the Office of Surveillance and Biometrics (OSB) at the FDA's Center for Devices and Radiological Health (CDRH). Ms. Dillard's broad medical device related expertise is based on over 20 years of medical device related experience in clinical, research, and regulatory settings. In her current position, she serves as an Agency expert on postmarket matters related to the review, analysis, and resolution of emerging public health problems involving both ionizing and non-ionizing radiation-emitting medical devices and nuclear medicine systems. Her other assigned device areas include all endoscopic equipment and accessories, in-vitro diagnostic devices, sterilization and disinfection systems and products and medical gloves. Her work frequently requires developing unique or novel solutions to resolve complex and often controversial issues raised in medical device adverse incident reports received by FDA.

Ms. Dillard received her M.S. in Technology Management at the University of Maryland. During her career she has co-authored a number of peer reviewed publications involving medical devices. Prior to her work at FDA she held a research position within the Applied Physics Section of the Clinical Center Department of Nuclear Medicine at the National Institutes of Health. Ms. Dillard maintains active national registries in nuclear medicine technology from the American Registry of Radiologic Technologists and the Nuclear Medicine Technology Certification Board.

Remarks
by
Cynthia C. Leggett
Office of Regulatory Affairs
For
CDRH Outside Leveraging Seminar
October 28, 1998

In the early 1980's, FDA's Center for Food Safety and Applied Nutrition (CFSAN), put new life into its industry education program by expanding the staff, funding information materials development and implementing industry education workshops across the country. Appropriate food and cosmetic industry segments were selected through reviews of violation rates and tools were developed to educate them on FDA law and regulations. A series of workshops were held using both print materials and audiovisuals aimed at particular industry segments in need of improvement. Unfortunately, funding for education activities was severely cut after a few years, but the responsibility to educate industry continued. So CFSAN had to look elsewhere for the financial support to carry out the mandate.

We approached several trade associations with the idea of co-sponsorship of materials development and implementation of educational workshops and seminars. Agreements were made and so was launched a program that continues today in a variety of areas. Following is a brief description of some of the efforts that resulted:

Industry Education Workshops

- Warehouse sanitation—with the National Pest Control Association, the American Warehouseman's Association and the American Institute of Baking
- Cosmetic Labeling—with the Independent Cosmetic Manufacturers and Distributors Association
- Airline Catering—with the In-Flight Food Services Association, Marriott Corporation, United Airlines, Sky Chefs, American Airlines, Dobbs Incorporated and Cornell University

Information and Audiovisual Materials Developed

- Warehouse Sanitation Manual—Using the "10 Rules for Warehouse Sanitation" theme, a manual of the Good Manufacturing Practices regulations, posters and other materials for use in training warehouse personnel—available for purchase from NAV/GSA.
- "10 Rules for Warehouse Sanitation"—Slide show with audio tape for use in training warehouse personnel—available for purchase from NTIS/GSA.
- Cosmetic Labeling Guide—Very comprehensive guide on myriad of cosmetic labeling requirements in clear, concise language—now available for purchase from the trade association

- Cosmetic Labeling Slides—To accompany labeling guide and for use in industry education workshops, also available for purchase from the trade association.
- "Safe Food Handling—You Are the Key"—A 10-module slide and audio production on safe food handling in airline catering facilities. Used the premise of a foodborne illness outbreak on an overseas flight and the resultant investigation throughout the different areas of the catering facility, i.e., food reception and storage, cold food prep, hot food prep, holding, transportation, etc. of how and why it happened. This slide show is now used worldwide, is available for purchase from the trade association and has been translated (by the caterers and airlines themselves) in Arabic, Spanish, French, Japanese, Norwegian and other languages.

Logistics

In co-sponsoring these efforts, we made very clear that FDA could not afford to carry out the programs without the industry's support and assistance—financial and otherwise. We pointed out to them the problems we were seeing in their particular areas, and assured them that we would provide FDA technical expertise and information to improve compliance rates. We also assured them that the agency would not take names and numbers and exact regulatory action against those who attended programs just because they attended. The trade groups made all arrangements for the workshops; did all mailings using labels from FDA's Official Establishment Inventory (OEI); printed most of the handout materials and collected any funds that were needed. FDA employees were allowed to attend the workshops at either reduced rates or at no cost. FDA provided FDA speakers and funded their travel.

On the manuals and audiovisuals, FDA provided technical expertise, writing skills, agency clearance, while the trade groups funded the costs of development and made them available for sale.

Benefits

The benefits accrued were immense. FDA saw a significant increase (in some instances over 95%) in the compliance rates of the affected industries. We were able to get our message out to many more individual firms than we could through routine inspections and regulatory actions. We improved our working relationship with the affected industries, particularly the trade associations. We gained credibility with the individual industry segments due in part to partnering with academia in some of the materials and AV development.

At the same time, the trade groups increased their membership and gained credibility by maintaining a good relationship with FDA. They provided a valuable service to their members and were able to stay up-to-date on the latest in FDA activities and regulations. In addition, the trade associations were able to better serve their members as "consultants to FDA."

Biography

CYNTHIA C. LEGGETT
Senior Public Affairs Specialist
Division of Federal-State Regulations
Office of Regional Operations
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane, Room 12-07
Rockville, MD 20857
(301) 827-2914
fax: (301) 443-2143

Mrs. Leggett began working for the Food and Drug Administration as a Consumer Affairs Officer in the Atlanta District Office in June 1974. In 1978, she transferred to the Office of the Commissioner in Rockville, MD as Writer/Editor and then as a Policy Analyst, assigned to food issues. In 1980, she transferred to FDA's Center for Food Safety and Applied Nutrition as Industry Information Officer. She was appointed to the Seafood Coordination Staff in 1990, which eventually became the Office of Seafood. She joined the Office of Regulatory Affairs in 1990 as Senior Public Affairs Specialist, responsible for representing and leading the Field PAS program. Previous experience included teaching in Augusta, Georgia and working as a Retail Food Inspector with the Florida Department of Agriculture and Consumer Services in Tallahassee, Florida.

She has a Bachelor of Arts degree in Sociology and Psychology from Augusta State University, Augusta, GA. Hobbies include hiking, canoeing, skiing, cooking wonderful things to eat, and bringing people together. She is married to Don Leggett and has one son, Timm, and four step children, Ted and Linda, Michelle and Marshall.

THIRD-PARTY RELATIONSHIPS
Resulting from the
MAMMOGRAPHY QUALITY STANDARDS ACT OF 1992 VC

PROBLEM: Certify 10,000 mammography facilities in 8 months

SOLUTION: Certify by accreditation pass-through

ACCREDITATION

A. Private, non-profit organizations (American College of Radiology)
B. State agencies (Iowa, Arkansas, California, State of Texas pending)

PROBLEM: Ensure same standards of mammography quality nationwide while delegating responsibilities to States

SOLUTION: Establish State Working Group to assist DMQRP in developing Demonstration Project and Regulatory Program

STATE CERTIFICATION

A. Delegated Authority
    1. Issue/renew certificates
    2. Suspend/revoke certificates
    3. Inspections
    4. Sanctions
B. Dual Authority
    1. Suspend/revoke certificates
    2. Sanctions
C. Performance-based Oversight Program
D. Demonstration Project
    1. Iowa, Illinois (1998-99)
    2. Application Announcement (1999-2000)
E. Regulatory Program (projected 2000)

PROBLEM: Radiology community wants regulations for interventional mammography. Surgeons would not meet requirements.

SOLUTION: Joint voluntary accreditation program established to improve standards.

VOLUNTARY STANDARDS FOR INTERVENTIONAL MAMMOGRAPHY
A. American College of Radiology
B. American College of Surgeons

MEMORANDUM

TO: Pat Spitzig

FROM: Ruth Fischer/DMQRP

DATE: October 26, 1998

RE: Brief Bio

Brief Resume: Ruth Fischer is the Chief of the Mammography Standards Branch within OHIP's Division of Mammography Quality and Radiation Programs. She received her Masters degree in health services administration from George Washington University. Prior to joining FDA in 1994, Ms. Fischer served as a Congressional Fellow to the Select Committee on Aging in the U.S. House of Representatives. She held positions with two policy institutes and spent several years as a consultant to the National Cancer Institute, where she specialized in state legislative and regulatory issues surrounding mammography quality assurance. The Division's third-party initiatives reside in her Branch.

PROBLEM:

Certify 10,000 facilities in 8 months

STORY:

Congress; Delegation; Statute

LESSONS LEARNED:

Don’t reinvent the wheel
Don’t duplicate effort
Know your limits
Capitalize on outside expertise

OBSTACLES:

Literal vs. Creative thinking

R/B to OL PARTNER:

Business as usual
Recognition

R/B to FDA:

Workload

PROBLEM:

Ensure same standards of mammography quality nationwide while delegating responsibilities to States

STORY:

Immediate implementation
Advisory Committee opposition

Constitution
State Working Group
Demonstration Project (Nuclear Regulatory Commission, OSHA, EPA)

LESSONS LEARNED:
Buy-in
Negotiate and compromise
Choose your battles
You can't do it by yourself OR networking is not a dirty word

OBSTACLES:
Adversial relationship
"One right way" thinking
Electronic communication

R/B to OL PARTNER:
Local control

R/B to FDA:
Increased workload
Credibility
Cooperation
Support

PROBLEM:

Radiology community wants regulations for interventional mammography. Surgeons would not meet requirements.

STORY:

Exempted from interim and final regs
180 shift in 2 years
Joint Task Force
Voluntary accreditation programs

LESSONS LEARNED:

Evaluate the squeaky wheel no matter how renowned
Anecdote is emotional; data is powerful

OBSTACLES:

Turf war

R/B to OL PARTNER:

Autonomy in medical practice
Standards established
Improve quality

R/B to FDA:

Decreased workload
Increase approval rating

Title of Project

HACCP for Medical Devices

Presenting Problem

FDA has dwindling resources to inspect the industry
FD promulgated a new reg for the industry recently
Industry finds our inspections long and costly (2-3 week average length)
Technology changes add to the challenge for both groups.

OL Story

A system of controls that has been used in other industries, e.g. the military, food production, and chemical production, HACCP, might be a way o engage the industry and the agency in a productive venture where all parties would focus on what is most critical about designing and producing medical devices. In fact the industry has been so interested they are out-pacing the agency: they have written and published a cover story in the 10/98 issue of the industry journal, Medical Device and Diagnostic Industry; testified that HACCP would work before Congress and have published a challenge to the rest of the industry on the internet to join them in trying HACCP on a pilot basis with FDA.

LESSONS LEARNED

- Industry and FDA can work together
- People in both groups can be open-minded. (People from both groups have attended Seafood HACCP courses and they see the applicability of a food control for devices).
- Industry can take a leadership role and even challenge the agency to do more.
- Industry, academics, trade associations, consumer representatives and state and local regulators can and have worked together on food HACCP.
- Training for regulators and industry can occur side-by-side in the same classroom.
- Industry employees can develop greater awareness and ownership of product safety.
- HACCP can become a marketing tool.
- Firms have reported fewer recalls, suits, product rejects, and less down-time.

OBSTACLES TO OVERCOME

- HACCP requires a mind shift.
- HACCP is preventative, not reactive.
- HACCP requires a new level of trust between the agency and industry.

RESULTS/BENEFITS FOR OL PARTNERS

- Training for regulators and industry can occur side-by-side in the same classroom.

- Industry employees can develop greater awareness and ownership of product safety.
- HACCP can become a marketing tool.
- Firms have reported fewer recalls, suits, product rejects, and less down-time.
- Benefits must override costs.

RESULTS/BENEFITS FOR FDA

- Industry can take a leadership role and even challenge the agency to do more.
- Industry, academics, trade associations, consumer representatives and state and local regulators can work together.

BIOGRAPHICAL SKETCH
ADRIANNE GALDI
DIRECTOR
DIVISION OF ENFORCEMENT 1
OFFICE OF COMPLIANCE
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

As Director, Division of Enforcement 1, Ms. Galdi is responsible for the regulatory activities of three branches in the specific areas of in-vitro diagnostics, diagnostic equipment (including radiation-producing electronic products), and general surgery devices. The mission of the Division of Enforcement 1 is to ensure compliance of medical devices with the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992 and the Radiation Control for Health and Safety Act of 1968. Ms. Galdi joined the FDA in 1977 as a regulatory officer in the X-Ray Products Branch, Division of Compliance, Bureau of Radiological Health. In 1983, she accepted a position as a senior scientific reviewer in the Radiology Devices Branch, Office of Device Evaluation, CDRH, where her area of expertise was hyperthermia for cancer therapy. In 1987, Ms. Galdi became the Chief, Radiology Devices Branch and in 1991 the Chief, Conventional Therapeutic and Radiological Branch, ODE. Prior to her appointment a Director, Ms. Galdi was the Acting Director, Division of Compliance Programs, Office of Compliance and Surveillance, CDRH.

Ms. Galdi holds a B.S. in Radiation Health Physics from Lowell Technological Institute, Lowell, Massachusetts, and an M.S. in Radiological Sciences and Protection from the University of Lowell. Currently, she is working on her doctorate in Public Health Administration from the University of Southern California.

Table 5. MILESTONE CHART/PROPOSED OBJECTIVES (_____Specific Activity and ----------Related Activity

1997	1st Year	1988	2nd Year	1999
A S O	N D J F M A M J J A S O N D J F M A J J			

Improve Training MATERIALS

1..----------? ?----------?_____?----------

Develop Additional Models

2. ?_____ ?----------?_____?----------

Advance Compendium of Methods

3. ?_____?----------

Technical Advisement

4. ?_____?----------

Train-the-Trainer Sessions

5. ?----------_____?----------?_____?----------

Conclusions

Safe and effective products are a responsibility the FDA shares with many others. Leveraging with others such as academia, industry and consumer organizations provides all involved with the opportunity to honor that shared responsibility and realize shared benefits. Over the years many creative people in FDA have "done more with less." Until recently, however, most people in the agency saw leveraging as an exception to the usual methods of accomplishing FDA's mission. This mental model limited most leveraging projects to perceived "low-risk" activities such as FDA encouraged / Industry initiated training, course development, etc. What is unique about the work described in this case study is that we in OSB named outside leveraging, defined it, systematized it and obtained organizational sanction to do it as a legitimate way to solve identified problems and / or improve public health outcomes. We also invited others in our Center and the Agency to join with us in exploring leveraging as a viable approach. This is very much in tune with our new Commissioner who has gone on record as wanting to be truthful about what the agency can and will do and the help we need from others to accomplish FDA's vital mission. Dr. Henney wants to share openly: information about and responsibility for public health with all our stakeholders. We believe outside leveraging will provide a welcome, effective and efficient means to accomplish the Agency's goals.

Sequel [in box]

One year plus after the seminar and initial workshop, we believe the seminar and follow-on activities were a useful mechanism to inspire and encourage our staff and managers to better understand and consider the potential of outside leveraging. The speakers challenged our assumptions about what leveraging is possible and helped us redefine the "our" in "our work" to include the stakeholders who share responsibility with us for protecting the public health.

Since the seminar we have learned even more. We have been surprised and gratified that people in industry have shown an interest in our pilot proposals. Not only have they been willing to explore possibilities, they have suggested how we might better work with them and how they might better work with one another…. all with the shared goal of better protection of the public health. The best outcome so far is that industry colleagues have offered to share with each other, via an FDA web page, information we had assumed they would carefully guard from each other as well as from FDA. We are delighted that Commissioner Henney established a Task Force in 1999 to institute leveraging as a primary strategy to accomplish the Agency’s mission. Dr. Henney’s emphasis on leveraging as a key means of accessing the diverse talents necessary to address emerging health concerns creates a fertile ground in which leveraging initiatives will flourish.
